Evidence Reports of Kampo Treatment

Task Force for Evidence Reports / Clinical Practice Guideline Committee for EBM, the Japan Society for Oriental Medicine

14. Genitourinary Tract Disorders (including Climacteric Disorders)

Reference

Iwabuchi S. Effect of kyuki-kyogai-to on stopping dysfunctional uterine bleeding – comparison with occidental hemostatic drugs -. *Nihon Toyo Igaku Zasshi (Japanese Journal of Oriental Medicine*) 2000; 50: 883-903 (in Japanese with English abstract). Ichushi Web ID: 2000172969 CiNii

1. Objectives

To evaluate the efficacy and safety of kyukikyogaito (キュウ帰膠艾湯) for menometrorrhagia.

2. Design

Quasi-randomized controlled trial (quasi-RCT).

3. Setting

Obstetric and gynecologic practitioner, Yamagata, Japan.

4. Participants

The analysis population included 183 out of 200 randomized patients with menometrorrhagia.

5. Intervention

Arm 1: administration of 9.0 g of TSUMURA Kyukikyogaito (キュウ帰膠艾湯) Extract Granules for 7 days (n=100). Ninety-three patients were included for analysis.

Arm 2: administration of tranexamic acid (3 tablets of Transamin) and carbazochrome/VK mixture (3 tablets of Ophtharum K) for 7 days (n=100). Ninety patients were included for analysis.

6. Main outcome measures

Number of days from exploratory endometrial curettage to hemostasis.

7. Main results

The time to hemostasis was significantly shorter in arm 1 (4.29 ± 1.54 days) than in arm 2 (5.45 ± 2.13 days). When response was determined by the criterion of 'hemostasis by day 7', the response rate was significantly higher (94.6%) in arm 1, compared with 72.2% in arm 2. By *sho* (\mathbb{H} , pattern), cases of hypofunction or intermediate function required significantly fewer days to hemostasis when receiving kyukikyogaito, whereas cases of hyperfunction showed no difference in the days to hemostasis between arms. By the appearance of the endometrium on imaging, cases of the proliferative phase or simple hyperplasia required significantly fewer days to hemostasis when receiving kyukikyogaito, whereas cases of stationary phase, atrophic phase and mixed proliferative/secretory phase or secretory phase showed no difference in the days to hemostasis between arms.

8. Conclusions

Kyukikyogaito is more effective for hemostasis in menometrorrhagia, compared with hemostatic drugs tranexamic acid and carbazochrome/VK mixture.

9. From Kampo medicine perspective

After, but not before, dosing, differential diagnosis of *sho* was made visually and by abdominal palpation, and it was concluded that kyukikyogaito is effective regardless of *sho*.

10. Safety assessment in the article

A 32-year-old patient complained of feeling bad after receiving 1 sachet of kyukikyogaito, and of stomach discomfort and nausea after receiving 2 sachets, and then discontinued the medicine after receiving 4 sachets and was switched to another drug.

11. Abstractor's comments

Various pathogenic mechanisms can cause menometrorrhagia in Kampo medicine, as in western medicine. Kyukikyogaito is a combination of a single medicine that acts on one of these mechanisms, called *shoninkyoson* (衝任虚損), and a hemostatic drug (In: *Jinguiyaolue* [金匱要略, *Synopsis of Prescriptions of the Golden Chamber*]). Presence of both responders and non-responders to this combination suggests that the disease has a more than one pathogenesis. Although this study is a quasi-randomized controlled trial, in which patients were alternately randomized and placed in the order of visitation, a certain efficacy of kyukikyogaito for menometrorrhagia is suggested.

12. Abstractor and date

Okabe T, 15 June 2007, 1 April 2008, 1 June 2010.